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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/890,936
Filing Date: November 07, 2001
Appellant(s): KORSGREN ET AL.

Sheridan Neimark
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 11, 2009 appealing from the Office action mailed May 22, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is substantially correct. However, Appellant has embellished the instant claims with regard to details that are lacking in the instant claims. For example, instant claim 4 is drawn to a method comprising transplantation of individually isolated islets cells that are coated with a clotting inhibiting agent comprising heparin or a fraction or derivative thereof. Appellant's brief suggests that there is a specific agent recited in the claim (e.g. Corline Heparin Conjugate). However, this specific coating agent is not disclosed in the instant claims. Again on page 7 of the Summary of Claimed Subject Matter, Appellant states that the claimed subject matter discloses "a conjugate of heparin to coat the islets" when in fact what is claimed is "heparin or a fraction or derivative thereof".

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Wagner et al. DE 196 23 440 A 1. (translation)

5,705,270 Soon-Shiong et al. 1-1998

Nomura et al. Unpurified Islet Cell Transplantation in Diabetic Rats, Transplantation Proceedings, Vol. 28 No. 3 (June 1996) pages 1849-1850.

Couser et al., The Effects of Soluble Recombinant Complement Receptor 1 on Complement-Mediated Experimental Glomerulonephritis, Journal of the American Society of Nephrology, Volume 5, No. 11 (1995) pages 1888-1894.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 8, 11 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner et al. DE 196 23 440 A 1.

Wagner et al. teach method of use of anticoagulants such as heparin, hirudin and Marcumar and derivatives thereof in connection with transplantation of insulin producing cells such as islets of Langerhans (see claim 8). The cells may be in the form of microencapsulated islets (see figure 1 and claim 10). The abstract for Wagner et al. teach that the immobilized material is insulin, proinsulin and/or organ cells of xenogenic or autogenic origin (islets of Langerhans, etc.) and the system contains an agent to inhibit or suppress blood agglutination, agglomeration antagonists, heparin, hirudin, marcumar and their derivatives. Wagner discloses that the islets may be microencapsulated. Additionally, if the cells are microencapsulated, they are first mixed with the anticoagulant material. This step of mixing the anticoagulant material anticipates the herein rejected claims. Regarding the term "incubation" in claim 27, dictionary.com defines incubate as "to maintain at a favorable temperature and in other conditions promoting development". The islet cells are mixed with the anticoagulant material, such as heparin, to suppress blood agglutination. This would encompass maintaining favorable conditions to promote development.

Claims 4, 8, 11 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Soon-Shiong et al. U.S. 5,705,270 A.

Soon-Shiong et al. teach microcapsules containing biological material such as islet of Langerhans cells coated with polymerizable materials (see abstract, see also claim 3). The microcapsules are covalently linked with heparin (see claim 5). Soon-Shiong et al. teach encapsulation of islets of Langerhans for treatment of diabetes

(column 4, lines 1-4) to prevent the detrimental effects of capsule instability on the encapsulated biologically active material e.g. loss of immunoprotection for the encapsulated material is minimized (column 3, lines 61-66). Additionally, note that there is no provision in the instant claims that deals with the immunosuppression issue, without which, the transplanted islet cells would be rejected (see Islet Transplant Info). The instant specification describes immobilizing heparin according to a method developed by Corline Systems AB disclosed in WO 93/05793 (page 4 of the instant specification). The heparin in WO 93/05793 appears to be immobilized (conjugated) with a polymer comprising a substantially straight-chained organic homo or hetero polymer having a number of functional groups distributed along the polymer backbone chain via which groups at least about 20 molecules (see page 7 of WO 93/05793). While Appellant asserts that the heparin is not in microcapsules, since Appellant is employing the Corline Heparin Conjugate, it appears that it is similarly coated, and as such, must form micro (or macro) capsules if Appellant has followed the technique of Corline Systems AB as recited in Appellants' specification. Regarding new claim 27 drawn to incubating the isolated islets in a solution of heparin, dictionary.com defines incubate as "to maintain at a favorable temperature and in other conditions promoting development". Although Soon Shiong does not teach "incubation", favorable conditions are maintained to promote polymerization of the heparin and islet cells.

Claims 4, 8, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Nomura et al.

Nomura et al. teach islet transplantation for the treatment of type I diabetes after the islets cells were collected and administered with various doses of heparin (page 1849, column 1, paragraph 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Appellant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 9 rejected under 35 U.S.C. 103(a) as being unpatentable over Soon-Shiong et al. U.S. 5,705,270 A and Wagner et al. DE 196 23 440 A 1 as applied to claims 4, 8, 11 and 27 above, and further in view of Couser et al. 1995.

Couser et al. teach that complement is a major mediator of tissue injury in several types of glomerulonephritis (see abstract) and that an inhibitor of complement activation, sCR1 has shown beneficial effects on several forms of tissue injury including xenograft transplantation (page 1892, column 1, 1st full paragraph).

Soon-Shiong et al. teach microcapsules containing biological material such as islet of Langerhans cells coated with polymerizable materials (see abstract, see also claim 3). The microcapsules are covalently linked with heparin (see claim 5). Soon-Shiong et al. teach encapsulation of islets of Langerhans for treatment of diabetes (column 4, lines 1-4) to prevent the detrimental effects of capsule instability on the encapsulated biologically active material e.g. loss of immunoprotection for the encapsulated material is minimized (column 3, lines 61-66). Wagner et al. teach method of use of anticoagulants such as heparin, hirudin and Marcumar and derivatives thereof in connection with transplantation of insulin producing cells such as islets of Langerhans (see claim 8).

One of ordinary skill in the art would have administered an inhibitor of complement formation such as sCR1 during islet transplantation since it was well known in the art at the time the invention was made that the formation of complement results in

tissue injury and that Couser et al. teach that an inhibitor of complement activation, sCR1 has shown beneficial effects on several forms of tissue injury including xenograft transplantation (page 1892, column 1, 1st full paragraph).

(10) Response to Argument

Claims 4, 8, 11 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner et al. DE 196 23 440 A 1

Appellant asserts that the phenomenon of islets being coated by a layer of platelets which subsequently develops into an organized thrombus has not been previously considered. In response, Wagner et al. teach transplantation of isolated islet cells (page 4) that are capsulated by microcapsulation (thin and closely fitting membranes) (page 7) and further teach the retardation of thrombus (page 10), expressly recognizing that platelet adhesion leads to the formation of thrombus as a result, wherein clinical application of anticoagulants, platelet aggregation inhibitors and plasminogen activators become necessary as a simultaneous treatment (pages 11-12). Thus, this does not appear to be a new discovery as alleged by the Appellant. Appellant asserts that the Wagner disclosure is not very clear but does not elaborate on which issues are unclear. Appellant states that heparin is not mentioned until claim 7 which depends from claim 6 drawn to suppression or prevention of agglomeration of the blood. Appellant further states that "there is no disclosure of how this is done". In response, clearly Wagner et al. recognize the problem of platelet adhesion and formation of thrombus and teach that anticoagulants (such as heparin in claim 7) are employed in the immobilization system to prevent blood agglomerization. A reasonable

interpretation of agglomerization is “clot” or “thrombus”. Appellant states that the microcapsules are made of organic material (polylysine complexed alginate). While this may be one option in the teaching of Wagner et al, the Appellant has ignored some details such as, that the "immobilized organic material” such as islets of Langerhans contains components which suppress or prevent agglomeration of the blood, such as heparin or its derivatives (see claims). Appellant asserts that “nowhere in Wagner is it even remotely suggested that the islets be coated in the sense of the present invention". The instant specification describes “immobilizing heparin” (page 6 of instant specification) according to a method developed by Corline Systems AB disclosed in WO 93/05793. The heparin in WO 93/05793 appears to be immobilized (conjugated) with a polymer comprising a substantially straight-chained organic homo or hetero polymer having a number of functional groups distributed along the polymer backbone chain via which groups at least about 20 molecules (see page 7 of WO 93/05793). While Appellant asserts that the heparin is only “coated" and not in microcapsules, it appears that the instant islets and the islets of Wagner are similarly coated, and as such, Appellants coated islets would form micro (or macro) capsules if Appellant has followed the technique of Corline Systems AB as recited in Appellants' specification.

Claims 4, 8, 11 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Soon-Shiong et al. U.S. 5,705,270 A.

Appellant asserts that Soon-Shiong et al. does not teach heparin in any of the examples and describes a “shot-gun” disclosure. In response, heparin is recited in claim 5 and claim 10 of the patent and further, a reference is not limited to working

examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982). Soon-Shiong et al. teach microcapsules containing biological material such as islet of Langerhans cells coated with polymerizable materials (see abstract, see also claim 3). The microcapsules are covalently linked with heparin (see claim 5).

Claims 4, 8, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Nomura et al.

Appellants remarks regarding Nomura, stating "it only discloses the use of heparin administered systemically and this is likely to generate bleeding complications" and "it does not disclose any treatment of the islets by incubation with heparin" are erroneous because Nomura et al. disclose administration of the islets with heparin, and as such the islets must be coated in heparin. Further, the instant specification does not detail a specific amount of time for the "incubation" or "preincubation" of the islets in heparin, thus the administration of the islets with heparin anticipates the instantly claimed coated islets.

In response to Appellant's arguments against Couser individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Couser et al. provides motivation to employ a complement inhibitor because it teaches that complement is a major mediator of tissue injury in several types of glomerulonephritis (see abstract) and that an inhibitor of complement activation, sCR1 has shown beneficial effects on several forms of tissue injury including xenograft

transplantation (page 1892, column 1, 1st full paragraph). One of ordinary skill in the art would have administered an inhibitor of complement formation such as sCR1 during islet transplantation since it was well known in the art at the time the invention was made that the formation of complement results in tissue injury and that Couser et al. teach that an inhibitor of complement activation, sCR1 has shown beneficial effects on several forms of tissue injury including xenograft transplantation (page 1892, column 1, 1st full paragraph).

Appellant refers to Wagner et al again and asserts that in contrast to Wagner et al., the instant islets are "treated" not encapsulated. In response, instant claim 4 recites that the islets are "modified by irreversible adsorption with a clotting inhibiting agent comprising heparin or a fraction or derivative thereof onto the surfaces of said islets, in that the islets are "coated". It is unclear to the Examiner how "coated" differs from "encapsulated". Regarding arguments drawn to the size of the shell, Appellant's argument is irrelevant to the claims instantly presented.

Appellant asserts that Wagner does not teach individually isolated islets. In response, Wagner et al. teach transplantation of isolated islet cells (page 4) that are capsulated by microcapsulation (thin and closely fitting membranes) (page 7). It is unclear how a coated cell differs from a capsulated cell. Regarding the incubation of the islets, without a definition in the instant specification of what is meant by "incubation" Wagner's "immobilized organic material" such as islets of Langerhans that contain heparin or its derivatives is reasonably interpreted as incubated cells. Appellant's unsupported statement asserts that there is no evidence whatsoever that the clotting

inhibiting agent of the Wagner reference acts to inhibit or reduce clotting, however the same "clotting inhibiting agents are employed in the instant invention. Products of identical chemical composition (i.e. heparin) can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. inhibition of clotting) are necessarily present.

Appellant asserts that the capsule material of Wagner et al. is utilized to avoid immunological reactions because "the capsule exhibits poor compatibility with blood". In response, Wagner et al. teach transplantation of isolated islet cells (page 4) that are capsulated by microcapsulation (thin and closely fitting membranes) (page 7) and further teach the retardation of thrombus (page 10), expressly recognizing that platelet adhesion leads to the formation of thrombus as a result, which clinical application of anticoagulants, platelet aggregation inhibitors and plasminogen activators become necessary as a simultaneous treatment (pages 11-12). Appellant repeats part of the Declaration of March 2, 2004 in that "the invention set forth in the present application is not based on the same principles, i.e. encapsulation,. as the Wagner et al. citation or the Soon-Shiong et al. citation, and further states that the coating according to the invention is absolutely not the same as encapsulating according to Wagner and Soon-Shiong. Appellant repeats that the coating of the instant invention results in a "linkage between the islets and the heparin, i.e., "coating". In response, without a definition of what is meant by "coating" in the instant specification, microcapsule or encapsulation or capsulation is an interchangable term with "coating" in that the microcapsule also coats

the islet cells. Arguments drawn to the size of the shell are irrelevant to the claims instantly presented. Appellant further states that the examiner is incorrect in alleging that the Corline Heparin Conjugate in instant example 3 is no different from Wagner because the Corline Heparin Conjugate does not lead to encapsulation. In response, the instant claim elements appear in the prior art in the same configurations (immobilized organic material such as islets of Langerhans with heparin or derivatives of heparin and a polymer), serving the same functions (transplantation of the isolated islet cells), to achieve the results suggested in prior art (to suppress or prevent agglomeration of the blood). The Declaration repeated on page 23 of the brief is insufficient to overcome the rejections because it refer(s) only to the system described in the above referenced application and not to the individual claims of the application. It is unclear what part of the Declaration the Appellant feels that the Examiner is "brushing off". Each of the Declarations submitted have been carefully considered and each argument answered. The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Appellant focuses on one example in Wagner where 3000 islet cells were implanted in two microporotic silicon catheters. In response, this is one embodiment of the Wagner invention. Wagner teaches isolated islet cells (see page 4), that form microcapsules (page 7) with heparin or heparin derivatives (claim 6). In response to Appellant's argument that the references fail to show certain features of Appellant's invention, it is noted that the features upon which Appellant relies (i.e., intraportal injection of isolated islets) are not recited in the rejected claim(s). Although the claims are interpreted in

light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is well established that the specification teaches an invention, whereas the claims define the **right to exclude**. *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 [227 USPQ 577] n.14 (Fed. Cir. 1985).

Appellant repeats the portion of the Declaration from April 4, 2007, citing that the "encapsulation" of Wagner and Soon Shiong are not in direct contact with the islets. In response, firstly, Appellant provides no evidence of this dead space, secondly, Appellant again argues features that are not claimed, and thirdly, the instant specification describes "immobilizing heparin" according to a method developed by Corline Systems AB disclosed in WO 93/05793 (page 4 of the instant specification). The heparin in WO 93/05793 appears to be immobilized (conjugated) with a **polymer** comprising a substantially straight-chained organic homo or hetero polymer having a number of functional groups distributed along the polymer backbone chain via which groups at least about 20 molecules (see page 7 of WO 93/05793). Appellant asserts that the Corline Systems does not use a heparin-alginate conjugate as in Soon-Shiong et al. In response, the Corline system, noted in the instant specification as the manner in which heparin is modified/immobilized, employs *inter alia*, chitosan; and since both alginate and chitosan are natural polymers, and both fit the description of claim 1 of Corline Systems, a substantially straight-chained organic polymer having a number of functional groups distributed along the polymer backbone chain, the modified heparin, being modeled after the Corline System's surface modified heparin, does not exclude

the heparin-alginate conjugate with islet cells as in Soon-Shiong et al. Claims are not construed in a vacuum, but rather in the context of the intrinsic evidence, viz, the other claims, the specification and the prosecution history. Appellent references a photomicrograph, submitted as evidence that the islets of the instant invention have heparin on the surface of the islets. This is not disputed, however, Appellant has not provided a side by side comparison that compares the prior art coated/encapsulated islets to the instantly claimed coated/encapsulated islets. Further, Appellant has made unsupported statements regarding "dead space" of Wagner and Soon-Shiong. Neither Wagner, nor Soon-Shiong teach dead space in the microcapsule. It is the position of the Examiner that the instant claim elements appear in the prior art in the same configurations (immobilized organic material such as islets of Langerhans with heparin or derivatives of heparin and a polymer), serving the same functions (transplantation of the isolated islet cells), to achieve the results suggested in prior art (to suppress or prevent agglomeration of the blood). Appellant alleges that the microcapsules of Wagner and Soon-Shiong is an insoluble polymer with a cross longitudinal network of bonds. This allegation is unfounded. The Examiner would welcome the Appellant to point to page and line to point out this attribute of the invention.

Regarding the Shapiro Declaration of December 10, 2007, Appellant asserts that “the adsorption of clotting inhibiting agent is quite different from islet encapsulation”, however Appellant doesn't specifically teach any particular difference other than the reference to the prior art (not sure which prior art) being drawn to encapsulation for the purpose of isolation of islets from immunological attack. In response, as recited supra,

Wagner et al. teach transplantation of isolated islet cells (page 4) that are capsulated by microcapsulation (thin and closely fitting membranes) (page 7) and further teach the retardation of thrombus (page 10), expressly recognizing that platelet adhesion leads to the formation of thrombus as a result, which clinical application of anticoagulants, platelet aggregation inhibitors and plasminogen activators become necessary as a simultaneous treatment (pages 11-12). Again Appellant asserts that Wagner recites an insoluble polymer shell, but does not provide page and line where this statement is found. Reference is made to the Shapiro Declaration in which it is alleged that Wagner differs from the instant invention because Wagner teaches an impenetrable shell. In response, this allegation is unsupported. In fact, Wagner teaches variations in the test parameters of the various polymer films (not shells), such as "permeability" (page 24) and further teaches “porous material” (claim 8). Appellant states that Wagner et al. "does not describe how heparin might be used in the Wagner system". In response, Wagner et al. teach that the heparin (claim 7) is employed in the immobilized organic material (claim 1) (such as islets of Langerhans cells, for example page 7). Appellant asserts that the Examiner's understanding of Wagner et al. "makes no sense because if cells of Wagner were first mixed with an anticoagulant and then encapsulated as proposed, the anticoagulant could not function because the anticoagulant would then be sealed within the microcapsule". In response, there is no teaching in Wagner et al. of a "shell" or "insoluble barrier shell" as proposed by Dr. Shapiro and the Appellant. Contrary to this assumption, Wagner et al. teach a porous material (claim 8) and further teach variations in the test parameters with consideration to “permeability” (page 24).

Appellant asserts that Soon-Shiong et al. differ because it discloses the microcapsulation of biological materials using, for example a polymerizable alginate or a composition thereof with polyethylene glycol. In response, Soon-Shiong et al. teach biological material (particularly islets of Langerhans) coated with polymerizable material such as polymerizable alginate OR a composite of alginate and PEG and biocompatible material (see abstract). Biocompatible material is defined as including heparin (column 6, line 60). Appellant states that "it is well known that the main reason for using encapsulation is to avoid immunological reactions", however, there is no supporting reference accompanying this statement. Soon-Shiong et al. teach that one of the reasons that the biological material is encapsulated to avoid detrimental effects of capsule instability as well as on the recipient, when capsules are introduced into the body under physiological conditions, i.e., loss of immunoprotection for the encapsulated biologically active material and another reason is to minimize the induction of fibrosis (column 3, lines 61-67). Further, heparin generally is not employed as an agent to prevent immunological reactions. Heparin is an anticoagulant. Products of identical chemical composition (i.e. heparin) can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. clot inhibition or reduction) are necessarily present. Appellant states that "The Examiner was not justified in speculating contrary to the statements of fact in the Declarations of record". No information is given as to which Declaration Appellant is referring to, however regarding the portion of the Declaration stated on page 36 of the

brief stating that the “coating" differs from encapsulation of the prior art and asserts that Wagner and Soon-Shiong are “capsule shells”, but fails to cite page and line as to where this language is found. Wagner et al. teach a thin film membrane (page 7), and the composition of Soon-Shiong et al. are in a variety of forms, e.g., gels, microcapsules and macrocapsules the the like. The gels can be prepared in the presence of one or more biologically active compounds so as to provide an immunoprotective “coating" (column 9, lines 1-11). Appellant asserts that Soon-Shiong et al. does not anticipate the instant invention and states that “Soon-Shiong only "mentions” heparin as a possible alternative compound for apparently forming the microcapsules”. In response, Soon-Shiong et al. not only teach heparin as one of the biocompatible materials employed (column 6, line 60), it specifically claims heparin (see claims 5 and 10). Claim 5 teaches that the microcapsules formed around the biologically active material (e.g., islet cells) is *inter alia,* heparin. Appellant asserts the difference between Corline’s heparin conjugate stems from its “heparin-amine conjugate”, however Corline's heparin conjugate can be conjugated with a polymer comprising a substantially straight-chained organic homo or hetero polymer having a number of functional groups distributed along the polymer backbone chain via which groups at least about 20 molecules (see page 7 of WO 93/05793). Appellant asserts that Soon-Shiong differs because in Example 25, there is an “elaborate procedure" involving co-extrusion and photo-crosslinking. In response, the claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients or steps. Appellant asserts that Soon Shiong does not teach irreversible adsorption. In response, Soon-Shiong et al. teach heparin as one of the biocompatible

materials employed (column 6, line 60 and claims 5 and 10). Claim 5 teaches that the microcapsules formed around the biologically active material (e.g., islet cells) is, *inter alia,* heparin. Products of identical chemical composition (i.e. heparin) can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. irreversible adsorption) are necessarily present.

Claims 4, 8, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Nomura et al.

Appellant argues that Nomura discloses only the use of heparin, administered systemically which is "likely to generate bleeding complications". Firstly, Congress has given responsibility to the FDA, not the PTO to determine whether drugs are sufficiently safe. Secondly, Appellant admits that the islets cells of the instant invention are administered with "heparin alone or with heparin that is modified with the Corline system" (see page 30 of brief). It is unclear to the Examiner how the heparin coated islets of the instant claims would not also generate bleeding complications because, as stated supra, it also teaches "individually isolated islets, treated with a clotting inhibiting agent, e.g. heparin **or** soluble Corline heparin conjugate.

Claim 9 rejected under 35 U.S.C. 103(a) as being unpatentable over Soon-Shiong et al. U.S. 5,705,270 A and Wagner et al. DE 196 23 440 A 1 as applied to claims 4, 8, 11 and 27 above, and further in view of Couser et al.

Appellant states that "the deficiencies of Wagner and Soon-Shiong have been pointed out above and Couser has not been cited to make up for those deficiencies" and further states that Couser is "irrelevant". It is unclear how to answer these allegations. Applicant should submit specific arguments pointing out disagreements with the examiner's contentions. Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Donna Jagoe /D. J./

Conferees:

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614

/Robert A. Wax/
Quality Assurance Specialist
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